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BY FEDERAL EXPRESS

Division of Dockets Management (HFA-305)  
U.S. Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: NDA 21-863; Ibuprofen Liquid Filled Gelatin Capsules  
200 mg; Ranbaxy Laboratories Ltd.

CITIZEN PETITION 2005P-0436 / AMENDMENT 1

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The undersigned, on behalf of Banner Pharmacaps Inc. of High Point, North Carolina ("Banner") submits in quadruplicate, pursuant to 21 U.S.C. § 355(c)(3)(A) (C) and 21 C.F.R. § 10.30, this Amendment No. 1 to Banner's Citizen Petition 2005P-0436 docketed on October 28, 2005.

A. ADDITIONAL ACTION REQUESTED

That, in addition to the relief already requested in Citizen Petition 2005P-0436, the Food and Drug Administration ("FDA") issue a ruling confirming that Section 505(b)(2) NDA 21-863 filed by Ranbaxy Laboratories Ltd. ("Ranbaxy") is subject to a 30-month stay of final approval, by virtue of Banner's timely commencement of a patent infringement action against Ranbaxy based on Ranbaxy's submission of this NDA containing a paragraph IV certification against listed U.S. Patent No. 6,251,426 ("the '426 patent").<sup>1</sup>

B. STATEMENT OF GROUNDS

1. On March 4, 2005, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), Ranbaxy amended its 505(b)(2) NDA 21-863 for ibuprofen liquid filled gelatin capsules 200 mg. to include a certification that Ranbaxy's ibuprofen drug product

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AMD 1

<sup>1</sup> The main request in this Citizen Petition is a ruling by FDA that Ranbaxy be required to maintain a certification against the '426 patent.

does not infringe the '426 patent. Ranbaxy made this certification at the direction of FDA, which informed Ranbaxy that a certification is required with respect to this patent because the patent is listed in the Orange Book for Banner's listed drug ibuprofen liquid filled gelatin capsules 200 mg. (Citizen Petition, Exhibit D, at 2).

2. On the same date as it made the paragraph IV certification, Ranbaxy sent notice of its submission of the NDA containing a paragraph IV certification to Banner, by first class mail, return receipt requested. Banner, owner of the '426 patent and holder of NDA 21-472 for the pertinent listed drug, received Ranbaxy's mailed notice on March 7, 2005.

3. On April 18, 2005, within 45 days after receiving Ranbaxy's notice, Banner commenced an action against Ranbaxy for infringement of the '426 patent in the U.S. District Court of the Middle District of North Carolina, pursuant to 35 U.S.C. § 271(e)(2)(A) and based on Ranbaxy's Section 505(b)(2) NDA submission.

4. On May 10, 2005, Ranbaxy sent a letter to FDA, attempting to withdraw its paragraph IV certification against Banner's '426 patent (Citizen Petition 2005P-0436, Exhibit D). On September 20, 2005, Ranbaxy's counsel wrote to FDA's counsel, contending that the agency had changed its position and that no certification is required for the '426 patent (Citizen Petition, Exhibit F).

5. Banner's instant Citizen Petition (filed on October 28, 2005 shortly after Banner learned of Ranbaxy's May 10 and September 20 letters via discovery in the patent infringement action) requests a ruling from FDA that Ranbaxy is required to maintain its paragraph IV certification against the '426 patent.<sup>2</sup>

6. More recently, according to a statement by Ranbaxy's counsel in the patent case to Banner's counsel, FDA has allegedly informed Ranbaxy that the agency does not consider the 30-month stay to be in effect.

7. If this statement is true, FDA is incorrect. By virtue of Banner's timely filed patent infringement action, final approval of NDA 21-863 is stayed for a period of 30 months from March 7, 2005, the date Banner received notice of

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<sup>2</sup> The Petition's grounds: (i) Banner's ibuprofen liquid filled gelatin capsules is the pharmaceutical equivalent of Ranbaxy's proposed drug product; (ii) the pharmaceutical equivalent is the listed drug; and (iii) a 505(b)(2) NDA applicant is required to make a certification as to Orange Book patents for the pertinent listed drug.

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Ranbaxy's NDA with a paragraph IV certification. This result is **compelled by** 21 U.S.C. § 355(c)(3)(A)(C), which provides in pertinent part:

"If the applicant made a certification described in clause (iv) of subsection (b)(2)(A), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (3)(B) is received. If such an action is brought before the expiration of such days, *the approval may be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (3)(B)...*"<sup>3</sup>

8. Ranbaxy must maintain a Paragraph IV certification against the '426 patent, for all the reasons set forth in the instant Citizen Petition filed October 28, 2005. Accordingly, the 30-month stay is and must remain in effect until its expiration, on September 7, 2007. By this amendment to its Citizen Petition, Banner asks FDA for a confirmatory written ruling to this effect.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By 

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<sup>3</sup> Sole exceptions to the 30-month duration of the stay occur where the Court orders a shorter or longer period because a party fails to reasonably cooperate in expediting the patent infringement action, or where the Court decides that the patent is invalid or not infringed earlier than the expiration of the 30-month period. Neither of these exceptions is pertinent here.